CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-831

CORRESPONDENCE

Electronic Mail Message

Date: 2/15/01 2:51:51 PM
From: kathleen.basmadjian (kathleen.basmadjian@pharma.Novartis.com)
To: janip
Subject: Foradil final revisons to packaging and labeling

Dear Parinda,

We have accepted all your PI and patient leaflet changes, and made a few typographical corrections, and a correction to the telephone # at the end of the patient instructions for use. We are also attaching the packaging components for which you requested revisions.

I am also including the revised phase 4 commitment letter.

We look forward to receiving your approval letter.

Best regards,
Kathy

PI and Pt leaflets:

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CONSULTATION RESPONSE
Office of Post-Marketing Drug Risk Assessment
(OPDRA; HFD-400)

DATE RECEIVED: January 11, 2000	**DUE DATE:** March 11,2000	**OPDRA CONSULT #:** 00-0021

TO: Robert Meyer, M.D.
Director, Division of Pulmonary Drug Products
HFD-570

THROUGH: Parinda Jani, Project Manager
HFD-570

PRODUCT NAME: Foradil Aerolizer (formoterol fumarate powder for inhalation) **NDA #:** 20-831	**MANUFACTURER:** Novartis Pharmaceuticals Corp. East Hanover, New Jersey 07936

SAFETY EVALUATOR: Carol Pamer, R.Ph.

SUMMARY: In response to a consult from the Division of Pulmonary Drug Products (HFD-570), OPDRA conducted a review of the proposed proprietary name "Foradil Aerolizer" to determine the potential for confusion with approved proprietary and generic names as well as pending names.

OPDRA RECOMMENDATION: OPDRA does not object to the use of the name "Foradil Aerolizer", but with reservation (see review). We have suggested a requirement that the manufacturer treat all postmarketing medication error reports or reports of potential errors as Expedited (15-Day) reports for the first 6 months of product distribution, regardless of patient outcome.

/S/ 3/14/2000
Jerry Phillips, R.Ph.
Associate Director for Medication Error Prevention
Office of Post-Marketing Drug Risk Assessment
Phone: (301) 827-3242
Fax: (301) 480-8173

/S/
Peter Honig, M.D.
Director
Office of Post-Marketing Drug Risk Assessment
Center for Drug Evaluation and Research
Food and Drug Administration

Associate Director
Drug Regulatory Affairs

59 Route 10
East Hanover, NJ 07936-1080

Tel: 973-781-3666
Fax: 973-781-3590
Internet: kathleen.basmadjian@pharma.novartis.com

NOVARTIS

February 15, 2001

Robert Meyer, MD, Director
Division of Pulmonary and Allergy
Drug Products/HFD-570
Office of Drug Evaluation II
Attn: Document Control Room 10B-03
Center for Drug Evaluation and
Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA 20-831
Foradil® Aerolizer™ (formoterol fumarate inhalation powder)

RESPONSE TO FDA REQUEST

Dear Dr. Meyer:

Reference is made to our pending NDA 20-831 for Foradil Aerolizer. Reference is also made to our teleconference on February 2, 2001 during which the Division requested that we commit to perform a phase 4 trial that includes Foradil 24 mcg twice daily, 12 mcg twice daily and placebo. At this time Novartis Pharmaceuticals Corporation commits to conduct this phase 4 trial according to the following timeline:

Submit draft protocol to the division for review.	Within 90 days after approval letter
Initiate first patient first visit	Within 12 months after approval letter
Provide final study report	Within 30 months after approval letter

As discussed during our teleconference, the duration of treatment will be 16 weeks and the primary endpoint will be serious asthma exacerbations. Novartis commits to include at least 500 patients per arm. Additionally, we understand that you expect to review our draft protocol summary and provide comments within 45 days.

If you have any questions or concerns, please contact me at 973-781-3666.

Best regards,

Kathleen Basmadjian

Kathleen Basmadjian, PhD
Associate Director
Drug Regulatory Affairs

Submitted in duplicate

Electronic Mail Message

Date: 2/15/01 5:11:34 PM
From: kathleen.basmadjian (kathleen.basmadjian@pharma.Novartis.com)
To: janip
Subject: Foradil Aerolizer approval

Dear Parinda,

As a follow-up to our telephone conference call yesterday, we are confirming that for Foradil Aerolizer sample packages, the "Use by" date is stamped on by Novartis prior to shipment. It is stamped directly onto the "Use by" sticker that is located on the carton exterior.

Should you have any questions, please call me or Kathy.

Regards,
Steph

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Electronic Mail Message

Date: 2/16/01 8:49:51 AM
From: carl.schlotfeldt (carl.schlotfeldt@pharma.Novartis.com)
To: janip
Subject: Foradil Aerolizer

Resending to make sure you received revised version.

Steph

Carl Schlotfeldt
02/16/2001 08:41 AM
To: janip@cder.fda.gov
cc:
Subject: Foradil Aerolizer

Dear Parinda,

As discussed yesterday, Novartis confirms that one batch of capsules (Lot # S0A001) will be packaged in blisters with text identical to that submitted on August 17, 2000 as part of the complete response. The other label components (pouch and carton) and all subsequent batches will be packaged in components with label text identical to that submitted on February 7, 2001 and amended on February 15, 2001.

Should you have any questions, please contact me.

Stephenie Barba
(973 781-7548)

Kathleen Basmadjian, PhD
Associate Director

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080
Tel. 973-781-3666
Fax. 973-781-3590

NOVARTIS

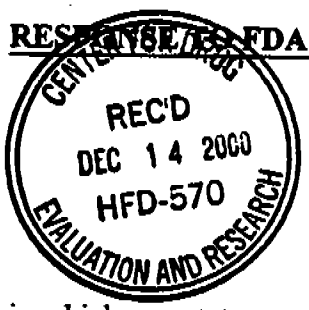
1S1
1-3-01

December 13, 2000

Robert Meyer, MD, Director
Division of Pulmonary and Allergy
Drug Products/HFD-570
Office of Drug Evaluation II
Attn: Document Control Room 10B-03
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA 20-831
Foradil® (formoterol fumarate inhalation powder)

RESPONSE TO FDA REQUEST



Dear Dr. Meyer:

Reference is made to your December 4, 2000 letter in which you state your concerns regarding the potential for confusion of Foradil with Toradol in handwritten prescriptions.

We would like to inform you that we intend to retain the use of the trademark Foradil for this product and will therefore provide with our launch materials, our proposal for educating and counseling health-care providers with regard to this potential confusion. We will also put in place a plan to expedite as 15-day reports, any post-marketing medication error reports or potential error reports regardless of patient outcome, as your letter requests for the first 6 months of product distribution.

If you have any questions or concerns, please contact me at 973-781-3666.

Best regards,

Kathleen Basmadjian

Kathleen (née Creedon) Basmadjian, PhD
Associate Director
Drug Regulatory Affairs

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-831

Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, New Jersey 07936

Attention: Kathleen Creedon, Ph.D.
Assistant Director
Drug Regulatory Affairs

Dear Dr. Creedon:

Please refer to your pending new drug application (NDA) dated June 24, 1997, received June 26, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Foradil Aerolizer (formoterol fumarate inhalation powder).

We have completed our review of the suggested tradename and have the following comments.

1. We have reservations about potential confusion of Foradil with Toradol in handwritten prescriptions. If, rather than choosing an alternate name, you plan to educate and counsel health-care providers with regard to this potential confusion, please submit a formal outline along with your planned launch promotional materials.

2. There will be a very low tolerance for reports of dispensing errors involving Foradil and Toradol, since such errors could have serious clinical consequences. FDA may require a name change in the future if such errors are reported.

3. Any post-marketing medication error reports or reports of potential errors should be submitted as expedited (15-day) reports for the first 6 months of product distribution, regardless of patient outcome.

We would appreciate your prompt written response so we can continue our evaluation of your NDA.

If you have any questions please contact Ms. Parinda Jani, Project Manager, at (301) 827-1064.

Sincerely Yours,

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

/s/

RobertMeyer
12/4/0011:27:26AM

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/S/

NDA 20-831

Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, New Jersey 07936

AUG 28 2000

Attention: Kathleen Creedon, Ph.D.
Assistant Director
Drug Regulatory Affairs

Dear Dr. Creedon:

We acknowledge receipt on August 18, 2000, of your August 17, 2000, resubmission to your new drug application (NDA) for Foradil Aerolizer (formoterol fumarate inhalation powder).

This resubmission contains additional information submitted in response to our May 24, 2000, action letter.

We consider this a complete class 2 response to our action letter. Therefore, the user fee goal date is February 18, 2001.

If you have any questions, contact me at (301) 827-1064.

Sincerely yours,

Parinda Jani
Project Manager
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 20-831

Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, New Jersey 07936

FEB 2 2000

Attention: Kathleen Creedon, Ph.D.
Assistant Director
Drug Regulatory Affairs

Dear Dr. Creedon:

Please refer to your pending new drug application dated June 24, 1997, received June 26, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Foradil (formoterol fumarate inhalation powder).

We also refer to your submission dated November 23, 1999.

Our review of the chemistry, manufacturing and controls (CMC) section of your submissions is complete, and we have identified the following deficiencies:

We are providing these comments to you before we complete our review of the entire application to give you preliminary notice of issues that we have identified. In conformance with the prescription drug user fee reauthorization agreements, these comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and subject to change as we finalize our review of your application. In addition, we may identify other information that must be provided before we can approve this application. If you respond to these issues during this review cycle, depending on the timing of your response, and in conformance with the user fee reauthorization agreements, we may not be able to consider your response before we take an action on your application during this review cycle.

If you have any questions, call Parinda Jani, Project Manager, at (301) 827-1064.

Sincerely yours,

/S/

Guirag Poochikian, Ph.D.
Chemistry Team Leader
Division of Pulmonary and Allergy Drug Products, HFD-570
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

NDA 20-831

Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, New Jersey 07936

Attention: Kathleen Creedon, Ph.D.
Assistant Director
Drug Regulatory Affairs

Dear Dr. Creedon:

We acknowledge receipt on November 24, 1999, of your November 23, 1999, resubmission to your new drug application (NDA) for Foradil Aerolizer (formoterol fumarate powder for inhalation).

This resubmission contains additional information submitted in response to our June 26, 1998, action letter.

We consider this a complete class 2 response to our action letter. Therefore, the user fee goal date is May 24, 1999.

If you have any questions, contact me at (301) 827-1064.

Sincerely yours,

Parinda Jani
Project Manager
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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NDA 20-831

MAR 25 1998

Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, New Jersey 07936

Attention: Kathleen Creedon, Ph.D.
Assistant Director
Drug Regulatory Affairs

Dear Dr. Creedon:

Please refer to your pending new drug application dated June 24, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Foradil (formoterol fumurate) Capsules for Inhalation.

We also refer to your amendments dated August 7 and 20, September 19, October 16 and 24, 1997, and February 5, and 24, 1998.

We have completed our review of the chemistry, manufacturing and controls (CMC) section of your submission and have identified the following deficiencies.

9 PAGE(S) REDACTED

We would appreciate your prompt written response so we can continue our evaluation of your NDA. Please note, however, that while we are providing these comments to you at this time in order to allow you as much time as possible to address them, providing a response to these comments will not necessarily preclude the issuance of an action letter.

If you have any questions, please contact Ms. Parinda Jani, Project Manager, at (301) 827-1064.

Sincerely yours,

Guirag Poochikian, Ph.D.
Chemistry Team Leader, DNDC II
Division of Pulmonary Drug Products (HFD-570)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Memorandum of Telephone Facsimile Correspondence

Date: January 17, 2001

To: Lynn Mellor
Regulatory Affairs

From: Parinda Jani
Project Manager

Through: Robert Meyer, M.D
Division Director /S/ 1/17/01

Subject: NDA 20-831/Foradil /Preliminary comments for the PPI

We are providing the attached information via telephone facsimile for your convenience, to expedite the progress of your drug development program. This material should be viewed as unofficial correspondence. Please feel free to contact me if you have any questions regarding the contents of this transmission.

Thank you.

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Memorandum of Telephone Facsimile Correspondence

Date: January 10, 2001

To: Kathy Creedon
Regulatory Affairs

From: Parinda Jani
Project Manager

Through: Robert Meyer, M.D. /S/
Division Director

Subject: Preliminary labeling comments for NDA 20-831/Foradil

We are providing the attached information via telephone facsimile for your convenience, to expedite the progress of your drug development program. This material should be viewed as unofficial correspondence. Please feel free to contact me if you have any questions regarding the contents of this transmission.

Thank you.

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Memorandum of Telephone Facsimile Correspondence

Date: November 3, 1998

To: Kathleen Creedon, Ph.D.
Assistant Director, Drug Regulatory Affairs

From: Parinda Jani
Project Manager

Through: John K. Jenkins, M.D., F.C.C.P. /S/ 11/4/98
Director, Division of Pulmonary Drug Products

Subject: NDA 20-831/Foradil Aerolizer
October 19, 1998, submission

We are providing the attached information via telephone facsimile for your convenience, to expedite the progress of your drug development program. This material should be viewed as unofficial correspondence. Please feel free to contact me if you have any questions regarding the contents of this transmission.

Thank you.

NDA 20-831
Foradil Aerolizer (formoterol fumurate inhalation powder)

We have given a preliminary review to your submission dated October 19, 1998, in response to our approvable letter dated June 26, 1998, and find the response incomplete. Specifically, the following items, listed in the order of our approvable letter dated June 26, 1998, were not addressed and need to be addressed before the user fee clock can be activated.

In addition, we acknowledge receipt of your "interim" clinical trial report for study #049, a twelve-month, double-blind, between-patient, placebo-controlled trial, comparing the safety, tolerability, and efficacy of 12 µg and 24 µg twice daily formoterol dry powder capsules for inhalation delivered by a single-dose inhaler (Aerolizer) in children with asthma in need of daily treatment with inhaled bronchodilators and anti-inflammatory treatment. Please be advised that a final study report with the SAS data file(s) will be required to be submitted to support the use of formoterol in children 6 – 12 years of age.

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